In the Claims

Please cancel claims 1-43.

Please add new claims 44-102 as follows:

44. A therapeutic composition comprising at least one peptide having a defined sequence of amino acid residues, said peptide comprising at least one T cell epitope for a protein antigen, said peptide being reproducible, being purified to at least about 90% purity and not being conjugated to any other molecule, said composition being capable of down regulating an antigen specific immune response directed against said protein antigen in a population of humans subject to said antigen specific immune response.

45. The composition of claim 44, wherein the peptide is purified to at least about 95% purity.

46. The composition of claim 45, wherein the peptide is purified to at least about 97% purity.

47. The composition of claim 44, wherein the peptide comprises less than 50 amino acid residues.

48. The composition of claim 47, wherein the peptide is at least about 12 amino acid residues in length.

49. A therapeutic composition comprising at least one peptide having a defined sequence of amino acid residues, said peptide being reproducible and comprising at least one T cell epitope for a protein antigen and having a mean T cell stimulation index of at least about 2.5 determined in an *in vitro* T cell proliferation assay with T cells obtained from a population of at least 30 humans sensitive to said protein antigen, said peptide being present in a dosage range of about 20 μg - 1.5 mg of peptide per dosage unit and said peptide not being conjugated to any other molecule, said composition being capable of down regulating an antigen specific immune response directed against said protein antigen.

50. The composition of claim 49, wherein the protein antigen is a protein allergen and the peptide has a mean T cell stimulation index of at least about 3.0.

51. The composition of claim 50, wherein the protein antigen is a protein allergen and the peptide has a mean T cell stimulation index of at least about 4.0.

52. The composition of claim 49, wherein the protein antigen is a protein allergen and the peptide has a positivity index of at least 150.

53. The composition of claim 49, wherein the peptide is purified to at least about 90% purity.

54. The composition of claim 53, wherein the peptide is purified to at least about 97% purity.

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55. The composition of claim 49, wherein the peptide is present in a dosage range of about 50 μg - 750 μg of peptide per dosage unit.

56. A therapeutic composition comprising at least one peptide having a defined sequence of amino acid residues, said peptide comprising at least about 20% of the T cell epitopes for a protein antigen, said peptide not being reproducible and not being conjugated to any other molecule, said composition being capable of down regulating an antigen specific immune response directed against said protein antigen in a population of humans subject to said antigen specific immune response.

57. The composition of claim 56, wherein the peptide is purified to at least about 90% purity.

58. The composition of claim 57, wherein the peptide is purified to at least about 97% purity.

59. The composition of claim 56, wherein the peptide comprises less than 50 amino acid residues.

60. The composition of claim 56, wherein the peptide is at least about 12 amino acid residues in length.

61. The composition of claim 56, wherein the population of humans includes at least 30 humans.

62. A therapeutic composition comprising at least one peptide having a defined sequence of amino acid residues, said peptide comprising at least one T cell epitope for a protein antigen and being present in a dosage range of about 20 μg - 1.5 mg of peptide per dosage unit, said peptide being reproducible and not being conjugated to any other molecule, said composition being capable of down regulating an antigen specific immune response directed against said protein antigen in a population of humans subject to said antigen specific immune response.

63. The composition of claim 62 wherein said at least one peptide is present in a dosage range of about 50 μg - 750 μg of peptide per dosage unit.

64. The composition of claim 62, wherein the peptide is purified to at least about 90% purity.

65. The composition of claim 64, wherein the peptide is purified to at least about 97% purity.

66. The composition of claim 62, wherein the peptide comprises less than 50 amino acid residues.

67. The composition of claim 66, wherein the peptide is at least about 12 amino acid residues in length.

68. The composition of claim 67, wherein the population of humans includes at least 30 humans.

69. The composition of claim 44, 49, 56 or 62, wherein said at least one peptide comprises at least two peptides.

70. The composition of claim 44, 49, 56 or 62, wherein said protein antigen is a protein allergen.

71. The composition of claim 70 wherein said protein antigen is a protein allergen selected from the group consisting of: a protein allergen of the genus *Dermatophagoides*; a protein allergen of the genus *Felis*; a protein allergen of the genus *Ambrosia*; a protein allergen of the genus *Lolium*; a protein allergen of the genus *Cryptomeria*; a protein allergen of the genus *Alternaria*; a protein allergen of the genus *Alder*; a protein allergen of the genus *Betula*; a protein allergen of the genus *Quercus*; a protein allergen of the genus *Olea*; a protein allergen of the genus *Artemisia*; a protein allergen of the genus *Plantago*; a protein allergen of the genus *Parietaria*; a protein allergen of the genus *Canine*; a protein allergen of the genus *Blattella*; a protein allergen of the genus *Apis*; a protein allergen of the genus *Cupressus*; a protein allergen of the genus *Juniperus*; a protein allergen of the genus *Thuya*; a protein allergen of the genus *Chamaecyparis*; a protein allergen of the genus *Periplaneta*; a protein allergen of the genus *Agropyron*; a protein allergen of the genus *Secale*; a protein allergen of the genus *Triticum*; a protein allergen of the genus *Dactylis*; a protein allergen of the genus *Festuca*; a protein allergen of the genus *Poa*; a protein allergen of the genus *Avena*; a protein allergen of the genus *Holcus*; a protein allergen of the genus *Anthoxanthum*; a protein allergen of the genus *Arrhenatherum*; a protein allergen of the genus *Agrostis*; a protein allergen of the genus *Phleum*; a protein allergen of the genus *Phalaris*; a protein allergen of the genus *Paspalum*; and a protein allergen of the genus *Sorghum*.

72. The composition of claim 71, wherein the protein allergen is selected from the group consisting of: *Der p* I; *Der p* II; *Der p* III; *Der p* VII; *Der f* I; *Der f* II; *Der f* III; *Der f* VII; *Fel d* I; *Amb a* I.1; *Amb a* I.2; *Amb a* I.3; *Amb a* I.4; *Amb a* II; *Lol p* I; *Lol p* II; *Lol p* III; *Lol p* IV; *Lol p IX* (*Lol p* V or *Lol p* Ib); *Cry j* I; *Cry j* II; *Can f* I; *Can f* II; *Jun s* I; *Jun v* I; *Dac g* I; *Poa p* I; *Phl p* I; and *Sor h* I.

73. The composition of claim 44, 49, 56 or 62, wherein said protein antigen is an autoantigen.

74. The composition of claim 73 wherein the autoantigen is selected from the group consisting of: insulin; myelin basic protein; myelinoligodendrocyte protein; rh factor; acetylcholine receptors; thyroid cell receptors; basement membrane proteins; thyroid proteins; ICA-69 (PM-1); glutamic acid decarboxylase (64K and 65K); Proteolipid protein (PLP); myelin associated glycoprotein (MAG); collagen (Type II); Heat Shock Protein; and carboxypeptidase H.

75. The composition of claim 44, 49, 56 or 62, wherein said at least one peptide is a cryptic peptide of said protein antigen.

76. The composition of claim 44, 49, 56 or 62, further comprising a pharmaceutically acceptable carrier.

77. The composition of claim 76 wherein said pharmaceutically acceptable carrier comprises at least one excipient selected from the group consisting of sterile water, sodium phosphate, mannitol, sorbitol, sodium chloride, and any combination thereof.

78. The composition of claim 44, 49, 56 or 62, wherein said composition is soluble in an aqueous solution at a physiologically acceptable pH.

79. A method of treating humans sensitive to an antigen comprising administering to a human at least one therapeutic composition of claims 44, 49, 56 or 62, in an amount sufficient to down regulate the antigen specific immune response in the human.

80. A method of treating humans sensitive to an antigen comprising administering to a human simultaneously or sequentially at least two compositions of claims 44, 49, 56 or 62, in an amount sufficient to down regulate the antigen specific immune response in the human.

81. The method of claim 84 wherein said administering comprises a route of administration selected from the group consisting of oral, intravenous, sublingual, transdermal, inhalation and rectal.

82. The method of claim 79 wherein said composition is administered in non-immunogenic form.

83. The method of claim 80 wherein said composition is administered in non-immunogenic form.

84. The method of claim 79 wherein said administering comprises subcutaneous administration of said composition.

85. The method of claim 80 wherein said administering comprises subcutaneous administration of said composition.

86. The method of claim 79 comprising administering an initial treatment of three to six dosages of said composition over a period of no more than 6 weeks.

87. The method of claim 80 comprising administering an initial treatment of three to six dosages of said composition over a period of no more than 6 weeks.

88. The method of claim 86 further comprising administering an additional administration of said composition at intervals of between about three months and one year after said initial treatment.

89. The method of claim 87 further comprising administering an additional treatment of said composition at an interval of between about three months and one year after said initial treatment.

90. The method of claim 79 wherein said initial treatment comprises increasing the dosage with each subsequent additional dosage of said composition.

91. The method of claim 80 wherein said initial treatment comprises increasing the dosage with each subsequent additional dosage of said composition.

92. The method of claim 79 wherein said initial treatment comprises decreasing the dosage with each subsequent additional dosage of said composition.

93. The method of claim 80 wherein said initial treatment comprises decreasing the dosage with each subsequent additional dosage of said composition.

94. A method of treating a human sensitive to a protein antigen comprising administering to a human sensitive to the protein antigen at least one therapeutic composition of claims 44, 49, 56 or 62 in an amount sufficient to achieve a statistically significant improvement in symptoms caused by the human's antigen specific immune response to the protein antigen.

95. A method of treating a human sensitive to a protein antigen comprising administering to a human sensitive to the protein antigen at least one therapeutic composition of claims 44, 49, 56 or 62 in an amount sufficient to achieve at least about 17.5% improvement, as compared to placebo, in symptoms caused by the human's antigen specific immune response to the protein antigen.

96. A method of treating a human sensitive to a protein allergen comprising administering to a human sensitive to the protein allergen at least one therapeutic composition of claims 44, 49, 56 or 62 in an amount sufficient to achieve at least about 9% improvement, as compared to placebo, in nasal symptoms caused by the human's allergen specific immune response to the protein allergen.

97. A method of treating a human sensitive to a protein allergen comprising administering to a human sensitive to the protein allergen at least one therapeutic composition of claims 44, 49, 56 or 62 in an amount sufficient to achieve at least about 17.5 % improvement, as compared to placebo, in lung symptoms caused by the human's allergen specific immune response to the protein allergen.

98. The method of claim 95, wherein the treatment results in at least about 23 % improvement.

99. The method of claim 95, wherein the treatment results in at least about 31 % improvement.

100. The method of claim 95, wherein the treatment results in at least about 28.5 % improvement.

101. A therapeutic composition comprising at least one purified peptide having a defined sequence of amino acid residues, said peptide being reproducible and purified to at least about 90% purity, said peptide not being conjugated to any other molecule and said peptide not being derived from a protein antigen to which the human is sensitive but being capable of mimicking a T cell epitope for a protein antigen to which the human is sensitive, said composition being capable of down regulating an antigen specific immune response directed against said protein antigen in a population of humans subject to said antigen specific immune response.

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102. A therapeutic composition comprising at least one purified peptide having a defined sequence of amino acid residues, said peptide being reproducible and purified to at least about 90% purity, said peptide being derived from an antigen which is a bystander antigen to the protein antigen to which a human is sensitive, said composition being capable of down regulating an antigen specific immune response directed against said protein antigen in a population of humans subject to said antigen specific immune response.

REMARKS

It is respectfully submitted that the objection and/or rejections of record do not pertain to the newly submitted claims. The cancellation of the previously pending claims should in no way be construed as an acquiescence to any of the outstanding objections and/or rejections. For the purpose of expediting prosecution, a response is provided below for each objection and/or rejection as it pertains to the newly submitted claims.

Personal Interview

The personal interview conducted between Elizabeth A. Hanley and Examiner Cunningham is gratefully acknowledged. The Examiner agreed during the interview that the teachings of Sehon et al. and Kuo et al. which are drawn to proteins do not pertain to peptides *per se* or the therapeutic compositions containing peptides presently being claimed.